UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re Bair Hugger Forced Air Warming Products Liability Litigation

MDL No. 2666 (JNE/FLN)

This Document Relates to
ALL ACTIONS

DEFENDANTS' MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE OR LIMIT THE TESTIMONY OF DR. MICHAEL A. MONT

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INTRODUCTION

Plaintiffs' motion to exclude the opinions and testimony of defense expert Dr. Michael A. Mont should be denied. Dr. Mont has the necessary expertise to render his opinions based on his over 30 years of experience as an orthopaedic surgeon, his incorporation of scientific literature on airflow-related infection reduction into his practice, and his analysis of applicable scientific literature upon which he bases his opinions. Although Plaintiffs' experts have opined that waste heat from the Bair Hugger system disrupts operating room airflow, they have failed to appropriately address the body of scientific literature regarding airflow disruption and heat generation from other sources such as people moving, doors opening and closing, and surgical cautery devices. *See, e.g.*, Doc. No. 751-1 at 279–83, Expert Report of Dr. Michael J. Stonnington ("Stonnington Rpt.") at 4–8. Dr. Mont's opinions that (1) many things in the operating room impact airflow, and (2) there are many sources of heat far in excess of any heat generated by the Bair Hugger, are proper rebuttal to Plaintiffs' experts, and will help the trier of fact resolve issues central to this litigation.

Dr. Mont's expertise. Dr. Mont is an orthopaedic surgeon, board certified by the American Academy of Orthopaedic Surgeons. DX1, Expert Report of Dr. Mont ("Mont Rpt.") at 1.[1] He is currently the Chairman of Orthopaedic Surgery at the Cleveland Clinic in Cleveland, Ohio and serves as the Department's Chief Administrative Officer, while

[1] All citations to "DX" in this Memorandum are exhibits to the concurrently filed Declaration of Peter J. Goss.

also performing surgeries, teaching, conducting research, and writing articles.[2] *Id.* at 2. He previously served as Director of the Center for Joint Preservation and Replacement, and as Co-Director of the Rubin Institute for Advanced Orthopedics (which he co-founded in 2000) at Sinai Hospital in Baltimore, Maryland. *Id.*

Before assuming his chairmanship on July 1, 2016, Dr. Mont performed approximately 500 to 700 joint replacement surgeries per year, totaling over 10,000 surgeries.[3] *Id.* He has extensive experience with and knowledge of the Bair Hugger system, as it was used in all of the surgeries he performed from 1989 through 2016.[4] DX2, Mont Dep. at 182:3-5. In those surgeries, he incorporated infection reduction practices based on guidance from the Centers for Disease Control (CDC) and scientific literature related to airflow in the operating room. Prior to his Chairmanship, Dr. Mont typically saw over 6,000 patients per year, with approximately half of them being related to knee replacements. DX1, Mont Rpt. at 2.[5] In addition to his extensive experience with patients,

[2] The Cleveland Clinic ranked #2 on the *U.S. News & World Report* Best Hospitals list for 2017–2018, and #3 on the *U.S. News & World Report* Best Hospitals for (Adult) Orthopaedics.

[3] As Chairman of the Department of Orthopaedics at the Cleveland Clinic, Dr. Mont performs approximately 350–400 surgeries per year.

[4] Dr. Mont no longer uses the Bair Hugger system because the Cleveland Clinic switched from the Bair Hugger system to the Stryker Mistral-Air Forced Air Warming System. The switch occurred before Dr. Mont arrived at the Clinic, but his understanding is that it was due to cost. DX2, Mont Dep. at 115:1–116:15. Notably, a recent study concluded that the Cleveland Clinic's rates of deep joint infection were lower with the Bair Hugger system than with the Mistral. DX1, Mont Rpt. Ex. E.

[5] Because of Dr. Mont's chairmanship, which has resulted in reduced clinical activity, he now sees approximately 3,000 patients per year.

Dr. Mont is a reviewer for over ten journals, and serves as the Associate Editor of the *Journal of Arthroplasty*—the top journal for hip and knee replacements.[6] *Id.* He is an accomplished author of over 730 peer-reviewed PubMed publications concerning lower extremity joint replacement; many of those publications are related to the topic of periprosthetic joint infections (PJIs). *Id.* at 3. Dr. Mont has also been a course director of numerous local, national, and international meetings that deal with hip and knee replacement surgery. Through those meetings, and his training and experience, Dr. Mont knows the standard of care for treating patients with multiple medical and surgical issues, including known complications from surgical procedures such as periprosthetic joint infections.[7] *Id*. at 2.

Dr. Mont's opinions. Based on his over 30 years of experience detailed above, as well as his analysis of relevant scientific literature, Dr. Mont offers several opinions in his expert report, including the following:

- The major source of PJIs is the patient's own skin;[8]

[6] As Associate Editor, Dr. Mont serves as the second in command at the journal.

[7] Dr. Mont's knowledge is garnered not only from his fellow panelists, but also from general orthopaedists in the audience when they review case reports of patients who have similar issues to the ones presented in this litigation.

[8] Plaintiffs misleadingly assert that Dr. Mont opines that the majority of PJIs are initiated by introducing micro-organisms during surgery. Pl. Mem. at 1. Dr. Mont opines that a patient's skin is the major source of PJIs, and that airborne transmission of bacteria plays a very minor role in the formation of PJIs. DX1, Mont Rpt. at 3, 6; DX2, Mont Dep. at 319:10–320:2. Plaintiffs also misleadingly state that Dr. Mont agrees that strategies should be utilized to decrease particulate and bacterial counts at the surgical site. Pl. Mem. at 1. Dr. Mont actually opined that no studies suggest that it takes only one or two CFUs to cause a SSI or PJI. DX2, Mont Dep. at 302:4–303:16; DX1, Mont Rpt. at 7.

- Particles are not the same as bacteria;
- Many things in the operating room impact airflow;
- There are many sources of heat generation in the operating room that are far in excess of any heat generated by the Bair Hugger system;
- HEPA filters do not reduce the bacteria that cause surgical site infections (SSIs);
- The McGovern odds ratio is fallacious for multiple reasons;
- Patient warming decreases SSIs and maintenance of normothermia has multiple benefits;
- The operating room is not sterile and contains many sources of bacteria (the sterile versus aseptic concept of the operating room environment);
- Variations in a surgeon's skill or technique can markedly influence infection rates; and
- The Bair Hugger system does not cause or contribute to PJIs.

DX1, Mont Rpt. at 3–19, Exhibits A–G.

By their own account, Plaintiffs challenge *only three* of Dr. Mont's opinions:

- His opinion regarding the potential airflow impact of other items in the operating room;
- His opinion that there are many sources of heat generation in the operating room more significant than the Bair Hugger system; and
- His deposition testimony that the Bair Hugger is not a possible source of contamination in the operating room.

Pl. Mem. at 6.

As further explained below, Dr. Mont has the necessary expertise, and properly relies upon his experience coupled with his review of the scientific literature, for his

opinions. Moreover, his opinions are proper rebuttal to Plaintiffs' experts and will help the jury evaluate central issues in the litigation. Accordingly, Dr. Mont's opinions are relevant and reliable, and therefore satisfy the requirements of Fed. R. Evid. 702, *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), and Minn. R. Evid. 702.

ARGUMENT

I. DR. MONT'S TESTIMONY AND OPINIONS ON SOURCES OF AIRFLOW AND HEAT GENERATION IN OPERATING ROOMS ARE RELIABLE.

A. Dr. Mont Properly Relies on His Experience and Review of Scientific Literature to Support His Opinions Regarding Airflow and Heat Sources in the Operating Room.

Dr. Mont opines that, even assuming Plaintiffs were correct in claiming that the Bair Hugger could impact airflow in the operating room, such impact would be infinitesimal in comparison to many other sources of airflow generation:

> The airflow generated by the Bair Hugger, as it emerges from the multiple perforations in the warming blanket, is very gentle. Moreover, the Bair Hugger is placed such that the air blows directly on the patient, underneath multiple drapes, and any airflow that emerges from under the drapes is so low in velocity that it has no impact on the air currents in an OR. This is especially true when one considers all of the other sources of air movement during surgery.
>
> In summary, any current created by the Bair Hugger would be negligible compared to these other sources, and therefore, should be considered non-existent.

DX1, Mont Rpt. at 10.

Dr. Mont identified the following sources of airflow during a typical orthopaedic surgery, including several which are directly at the operative site: surgeon traffic; the surgeon performing the procedure and creating continual air currents directly at the

operative site; one to three surgical assistants in lower extremity replacement procedures creating continual air currents directly at the operative site; nurse or surgical technicians handing out instruments and assisting with the procedure; circulating nurses handing out instruments, prostheses, etc.; the operating room team including anesthesiologists and others that enter room to deliver blood, etc.; doors opening and closing creating wind currents; moving of lights and other equipment by the surgeon or team; and equipment that generates air currents, including those that have cooling fans. *Id*. at 9.

1. Dr. Mont has the necessary expertise and experience to render his opinions.

Despite Dr. Mont's extensive experience, Plaintiffs claim that he cannot opine on airflow or heat generation because he is not an engineer, has never taken a class in fluid dynamics or heat transfer, and does not know the volume of flow required to disrupt the protective effect of airflow in an operating room. Pl. Mem. at 6–7, 9. Dr. Mont does not have to be an engineer or to have taken classes to opine on sources of airflow and heat generation in the operating room. As an orthopaedic surgeon, Dr. Mont has performed thousands of surgeries in operating rooms, experiencing firsthand the airflow disruption and heat generation he reports from various sources, including surgical equipment, staff movement during procedures, and doors opening and closing from people entering and exiting. Dr. Mont's 30-year career, during which he incorporated infection reduction practices based on scientific literature into the over 10,000 surgeries he performed, as well as his writing, analysis and editing of scientific literature on infection reduction, provide

the necessary expertise forum to render his opinions. *See* Fed. R. Evid. 702; *Wheeling Pittsburgh Steel Corp. v. Beelman River Terminals, Inc.*, 254 F.3d 706, 715 (8th Cir. 2001).

2. Dr. Mont properly relies on his experience, coupled with his analysis of relevant scientific literature, to support his opinions.

Numerous peer-reviewed publications conclude that moving people and opening and closing doors generate airflow currents in operating rooms, and even the United States Centers for Disease Control (CDC) issued infection reduction guidance that recommends minimizing such movement.[9] Although space limitations prevent a full analysis and recitation of all of the literature Dr. Mont relied on, the following are a few examples of the airflow-related publications cited in Exhibit A to his report (DX1, Mont Rpt. at 20–28):

- Andersson et al., "Traffic flow in the operating room: An explorative and descriptive study on air quality during orthopedic trauma implant surgery," 40(8) *Am. J. Infection Control* 750 (2012). The authors concluded that "[t]raffic flow has a strong negative impact on the OR environment. The results of this study support interventions aimed at preventing surgical site infections by reducing traffic flow in the OR." *Id*. at 750. The authors stated that "the most important source of airborne contamination is related to the dispersal of particles from persons present in the OR and their movements." *Id*. at 751.

- Alijanipour et al., "Operative Environment," 32 *J. Orthop. Res.* S60 (2014). In response to question 5, "What strategies should be implemented regarding OR traffic?," the consensus reached by 100% of the delegates was "we recommend that OR traffic should be kept to a minimum." *Id*. at S61. The authors also stated that "[p]ersonnel are the major source of air contamination in the OR, both by traffic that creates turbulence and contaminates ultraclean air and by bacterial shedding." *Id.* The publication examines and reviews numerous published articles which addressed the impact of traffic on the OR, including Andersson (referenced above), Quraishi, (which recognized a

[9] Mangram, et al., "Guideline for Prevention of Surgical Site Infection, 1999," 20(4) *Infection Control & Hosp. Epidemiology* 247, 260, 267 (1999). During his deposition, Dr. Mont explained several times that he relied upon scientific literature to support his conclusions. *See, e.g.*, DX2, Mont Dep. at 244:15–247:11.

direct correlation between the activity level of operating room personnel and bacterial fallout in the sterile field), Panahi et al. (which observed door openings during primary and revision TJA cases), and Lynch et al. (which showed an exponential relationship between number of door openings and the number of personnel in the OR). *Id.* In response to question 6, "Should operating lights be controlled with a foot pedal as opposed to reaching above eye level?," the consensus reached by 91% of the delegates was "[w]e recommend a general awareness that light handles can be a source of contamination and to minimize handling of lights as much as possible." *Id.*

- Brohus et al., "Influence of movements on contaminant transport in an operating room," 16 *J. Compilation* 356 (2006). Through Computational Fluid Dynamics (CFD) modeling, the authors concluded that "the influence of movements might cause a local but serious risk of transport of bacteria from the non-clean zone to the clean zone." *Id*. at 371.

- Chow & Wang, "Dynamic simulation on impact of surgeon bending movement on bacteria-carrying particles distribution in operating theater," 57 *Building & Env't* 68 (2012). The authors concluded that surgeons' bending their backs can cause excessively high concentrations of airborne bacteria carrying particles within the surgical zone, and that certain back-bending movements posed a higher risk of infections. *Id*. at 79–80.

- Kucukdurmaz et al., "Domestic electric drills in the service of orthopaedic surgery: a potential and preventable source of surgical site infections," 46(6) *Acta Orthop. Traumatol Turc.* 455 (2012). The authors concluded that domestic electric drills increased particles in the operating room and may be a source of surgical site infections. *Id*. at 458–59.

- Sagi et. al., "Compressed-Air power tools in orthopaedic surgery: Exhaust air is a potential source of contamination," 16(10) *J. Orthopaedic Trauma* 696 (2012). The authors stated, "Exhaust from compressed-air power tools in orthopaedic surgery may contribute to the dissemination of bacteria onto the surgical field. We do not recommend the use of compressed-air power tools that do not have a contained exhaust." *Id*. at 696.

- Smith et. al., "The effect of Laminar air Flow and door openings on operating room contamination," 28(9) *J. Arthroplasty* 1482 (2013). The authors concluded that protocols needed to be developed and implemented to reduce operating room door openings and diminish infection rates. *Id*. at 1485.

Dr. Mont explained during his deposition that he relies upon scientific literature in his practice, and as an orthopaedic surgeon who cares for patients with infections, it is important for him to have a working knowledge of numerous topics. DX2, Mont Dep. at 250:3-18. As the surgeon who is ultimately responsible for and aware of everything that occurs in an operating room, Dr. Mont can give opinions by relying on his experience, coupled with his analysis of relevant scientific literature. DX2. Mont. Dep. at 279:4-16. *See Block v. Woo Young Med. Co.*, 937 F. Supp. 2d 1028, 1042 (D. Minn. 2013) ("It is a commonly accepted methodology to examine literature in one's field and draw conclusions from it, and expert opinions may be based on professional studies as well as personal experiences."). As the *Kumho Tire* Court emphasized, the *Daubert* analysis is a "flexible one," and an expert's opinion may be based on "professional studies or personal experience." *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 150, 152 (1998); *see also Pipitone v. Biomatrix, Inc.*, 288 F.3d 239, 245–50 (5th Cir. 2002) (reversing the district's exclusion of the testimony of the infectious disease doctor who conducted a literature search); *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 412 (S.D.N.Y. 2016) (finding that experts need not conduct studies of their own in order to opine on a topic; a review of other studies and scientific literature can be enough to qualify experts to testify and to make that proposed testimony reliable).

In addition, Dr. Mont has incorporated principles from and relied on scientific literature related to infection reduction (including studies relating to reduced airflow) in his extensive years of practice. During his deposition, Dr. Mont shared one such example. He explained that, as part of Sinai Hospital's infection reduction efforts, the infectious diseases

department recommended reducing movement of people and opening and shutting doors in operating rooms in order to minimize the air currents generated by such movement. DX2, Mont Dep. at 245:17–247:16. Plaintiffs incorrectly argue that Dr. Mont provided no scientific basis for his opinions with respect to the effect on the downward airflow by moving objects "except that he read some articles." Pl. Mem. at 6. The scientific literature strongly supports Dr. Mont's opinions, which also draw from the decades he has spent in orthopaedic operating rooms.

3. Dr. Mont's testimony and opinions on sources of heat in the operating room are properly grounded in his experience and scientific literature.

Dr. Mont opined that there are many sources of heat in the operating room that generate heat far exceeding any heat generated by the Bair Hugger system. DX1, Mont Rpt. at 10–11. He explained,

> For example, 4 people involved in the operating room, as well as being much closer to the operative site than a Forced Air Warmer, generate much more heat than the Forced Air Warmer, and there are many more heat sources closer to the field. Heat from the Forced Air Warmer is further away from the field and would be dissipated by approximately the inverse square (1/r2) of the distance, so once again, it would have negligible to no effect.

Id. at 10. Dr. Mont also identified numerous other sources of heat in the operating room during lower extremity joint replacements, including (1) saw blades on bone—with the bone cutting action generating heat; (2) batteries that power the saw blades; (3) hooded gowns with battery packs (space suits) which have air blowing in them; (4) general overhead lights; (5) focused overhead lights directly at field (usually two); (6) ancillary

hooded lights that many surgeons wear (and the light generating unit); (7) all personnel in the operating room, including the patient, operating surgeon, direct assistants (often two to four), anesthesiology team (often two), circulating nurses, preparation help, and assistants (often two); (8) the machine to process fluid irrigation fluids—vacuum canisters and more substantial canisters; (9) other power sources for special blades used in some surgeries (more often in revisions) for burring bone, cement, etc.; (10) Anspach/Midas Rex devices; (11) standard electrocautery devices; (12) ancillary cautery devices (Plasmablade, Aquamantis, Canady, etc.); and (13) various ancillary devices in the operating room that vary by anesthesiologist, *e.g.*, defibrillator, computer, monitor, and anesthesia machine. *Id*. at 10–11.

In his over 30 years of experience as an orthopaedic surgeon, Dr. Mont has written several articles that discuss heat generation by electrocautery and other equipment, and has reviewed and relied upon countless others. A sample of the articles Dr. Mont relied upon, and which were cited in Exhibit A to his report (*id.* at 20–28), are listed below:

- Brace et al., "The air that we breathe' assessment of laser and electrosurgical dissection devices on operating theater quality," 43(39) *J. Otolaryngology—Head & Neck Surgery* 1 (2014). The authors state that tissue dissection devices (lasers, electrocautery) create surgical smoke caused by heating tissues to their boiling point, and that surgical smoke releases particulate matter into the operating room. *Id*. at 1.

- Chow et al., "The Integrated Effect of Medical Lamp Position and Diffuser Discharge Velocity on Ultra-clean Ventilation Performance in an Operating Theater," 15(4) *Indoor & Built Env't*, 315 (August 2006). In the study, a Computational Fluid Dynamics (CFD) model was used to investigate whether supply velocity and medical lamp positions will have a serious impact on the movement of infectious particles in an operating room. As part of the CFD model, the authors recognized various heat sources in the operating room: the patient (100W), surgical staff (100W each), two medical

lamps (250W each) and two pieces of medical equipment (650W each). *Id*. at 316–17.

- Shahi et al., "Bacterial Contamination in Tips of Electrocautery Devices During Total Hip Arthroplasty," 30(8) *J. Arthroplasty* 1410 (2015). Described as the first study to demonstrate that electrosurgical devices can become contaminated during total hip arthroplasties (THA) in laminar flow rooms, the authors discussed the fact that electrosurgical devices can be a potential reservoir for bacteria although they produce heat, and can be superheated to a temperature greater than 200˚C (392˚F). *Id*. at 1410, 1414.

Plaintiffs' assertion that Dr. Mont is not an expert in airflow engineering or thermodynamics and therefore cannot specify the heat these items produce is unavailing. Pl. Mem. at 10. Plaintiffs' claims that Dr. Mont is confused because he references heat sources above the table are incorrect. Indeed, heat sources above the table are closer to the surgical site and support Dr. Mont's opinion that heat from the Bair Hugger would be dissipated by the distance. *Id*., DX1, Mont Rpt. at 10. Furthermore, Plaintiffs incorrectly claim that Dr. Mont does not know the amount of heat the Bair Hugger system produces. *Id.* Although Dr. Mont could not remember the exact wattage at his deposition, he testified that he knows the amount in relation to what is generated per person and previously reviewed the Bair Hugger manual. DX2, Mont Dep. at 263:22–264:12.

Dr. Mont appropriately based his opinion on various heat sources in the operating room on his experience and peer-reviewed publications on the topic, including articles he authored and edited.

II. DR. MONT'S OPINIONS ON FORCED AIR WARMING SYSTEMS ARE RELIABLE.

A. Dr. Mont's Opinion that the Bair Hugger Is Not Capable of Causing PJIs Is Reliable.

Plaintiffs argue that Dr. Mont should be precluded from testifying that the Bair Hugger is not a potential source of contamination in the operating room. What Dr. Mont actually opined in his report, however, is that "use of the Bair Hugger does not cause PJIs nor does it contribute in any way (let alone in a substantial way) to the risk of developing a PJI." DX1, Mont Rpt. at 19. When asked during his deposition whether he would agree with the proposition that patient warming devices are potential sources of contamination in the operating room, Dr. Mont answered, "No, I don't agree with that." DX2, Mont Dep. at 108:1-10.

Throughout his report, Dr. Mont offers detailed opinions supporting his deposition testimony that forced air warming systems are not potential sources of contamination in operating rooms. *See generally* DX1, Mont Rpt. at 7–9, 13–16. Instead of addressing the substance of Dr. Mont's opinions, Plaintiffs essentially argue that he should be precluded from testifying that the Bair Hugger is not a potential source of contamination in the operating room because he is being compensated by Defendants, framing his testimony for their benefit, and therefore cannot be believed. Moreover, despite the lengthy analysis in his report, Plaintiffs claim that "neither in his report nor in his deposition did Dr. Mont identify any evidence whatsoever that the items he believes are other 'potential sources of

infection' actually have the capability to increase infection risk in the operating room."[10] Pl. Mem. at 11. Plaintiffs' claims are belied by Dr. Mont's report, including the sections titled "Particles are not the same as bacteria," and "Odds ratio of 3.8 for an infection using the Bair Hugger device in the McGovern, et al. study is fallacious for multiple reasons."[11] Dr. Mont performed a thorough analysis of the scientific literature, including the studies upon which Plaintiffs rely, and concluded that the Bair Hugger system is not capable of causing PJIs. *See* DX1, Mont Report at 7–9, 13–16.

1. Particles are not the same as bacteria.

As Dr. Mont explained, the scientific literature shows that only a small minority of particles carry bacteria, and particles are generally a poor surrogate for bacteria. *Id*. at 7. He further explained that Plaintiffs' experts rely on experiments conducted by employees and agents of the manufacturer of a competitive warming device that purport to show that using the Bair Hugger can increase particle counts. *Id*. Dr. Mont said in the absence of any other information, these findings would warrant further investigation to see if the demonstrated increase in particle counts correlates with an increase in bacteria. *Id*. Dr.

[10] The "other potential sources of contamination" that Plaintiffs mention in this section of their brief are the skin of the patient, movement and air flow in the operating room and a number of devices found in the room, such as suction tips, blades, saws, light handles, etc. Pl. Mem. at 10–11. Dr. Mont provides a lengthy and well supported analysis of his opinion, which is based on his experience, his research, and his articles showing that advanced skin preparation can reduce the incidence of PJIs by 60–70% or more. DX1, Mont Rpt. at 3–7.

[11] McGovern compared rates of deep joint infections in a hospital in the United Kingdom for 20 months when the Bair Hugger system was used exclusively versus 7 months when the HotDog system was used exclusively. Using a univariate logistic regression, the authors concluded that there was a significantly increased odds ratio (OR) for surgical site infections during the Bair Hugger system period (OR = 3.8, p=0.024).

Mont then explained that there are now nine published studies which have actually examined whether the Bair Hugger system causes an increase in bacteria and found that it does not. *Id.* at 7–8. He further explained that on at least seven occasions, researchers connected to Dr. Augustine failed to demonstrate that use of the Bair Hugger increased bacteria.[12] In summary, Dr. Mont stated,

> Plaintiffs' experts rely on the assertion that particles are a valid surrogate for bacteria generally (which, as discussed above, is itself an inaccurate proposition) and then make the unsupported assumption that, because a handful of experiments demonstrated that the Bair Hugger could, under certain experimental conditions, increase particle counts, then it must also be increasing bacteria. Plaintiffs' experts make this leap without regard to the weakness in the claim that particles can be a valid surrogate for bacteria in general, and without regard to the 16 consistent studies that demonstrate that the Bair Hugger device, regardless of its impact on particle counts, does not increase the bacterial bioburden. Bacteria cause PJIs, not particles. Plaintiffs' efforts to take the weak and controversial evidence that particles may be used as surrogates for bacteria, combine that with limited experimental evidence that the Bair Hugger may increase particles, and then conclude that the Bair Hugger does in fact increase bacteria, in the face of at least 16 studies to show that it does not, is pure sophistry and does not comport with valid scientific methodology.

DX1, Mont Rpt. at 8.

[12] Dr. Mont explained that although these seven studies involved the same authors who published studies purporting to show the Bair Hugger increases particle counts, the authors did not publish their findings showing that the Bair Hugger did not increase bacteria. DX1, Mont Rpt. at 8.

2. The McGovern study's odds ratio of 3.8 for Bair Hugger infections is fallacious for multiple reasons.

Dr. Mont also thoroughly reviewed the McGovern study, which Plaintiffs' experts rely on as proof that using the Bair Hugger system leads to increased PJIs. Dr. Mont opined that the reduction in infection rates shown in the McGovern study can be explained by the Hawthorne Effect (that individuals behave differently when being observed), regression to the mean, and most importantly by multiple real confounding factors. DX1, Mont Rpt. at 13. He explained that the Hawthorne Effect operated because an educational program was introduced to the entire staff in an effort to reduce infection rates, and individuals being observed will perform differently—wash hands more often, take more care in what they do (and these improved forms of "aseptic technique" will invariably lead to reductions in PJI rates). *Id*. at 13–14. He further explained that the high infection rates during the early part of the study period would also most certainly have experienced a regression to the mean and been reduced. *Id*. at 14. Lastly, Dr. Mont provided a detailed analysis on what he deemed most important: the multitude of not only hypothetical, but real, confounding factors that led to the high reported rates of the Bair Hugger system when compared to the HotDog system. He concluded,

> In summary, when parallel patient populations were compared, they were not statistically different. This is why for the vast majority of the time period, one is not comparing apples to apples, but rather apples to so many different factors, which makes conclusions about the Bair Hugger device from a single observational study completely erroneous. One could have picked any one of the 20 other factors that were changed and reached the same conclusions about that particular factor.

DX1, Mont Rpt. at 16.

B. Dr. Mont's Opinions That Warming Decreases Surgical Site Infections and That Normothermia Has Multiple Beneficial Effects Are Reliable and Grounded in Scientific Literature.

In his expert report, Dr. Mont explained that patient warming decreases surgical site infections, and that normothermia has multiple beneficial effects. DX1, Mont Rpt. at 17. Plaintiffs argue that Dr. Mont lacks the expertise to opine that normothermia or forced air warming prevents infections or deceases infection risks. Pl. Mem. at 12. Wholly ignoring Dr. Mont's detailed analysis in his report, which explains his reliance on a well-established body of scientific literature, including Kurz (1996), Melling (2001), and Allen & Jacofsky (2017), Plaintiffs incorrectly claim that Dr. Mont summarily reaches his conclusions without scientific basis. *Id.* Plaintiffs also incorrectly assert that Dr. Mont acknowledged at his deposition that there is no published study which supports the conclusion that forced air warming decreases infection risk. *Id.* Dr. Mont actually testified that, knowing the risks of hypothermia, such as hematomas and bleeding (which could lead to infection), it would be unethical and unconscionable for anyone to ever do such a study on patients. He testified that he has written articles showing forced air warming is very effective in maintaining normothermia, and that forced air warming is recommended by the Association of PeriOperative Registered Nurses, the International Consensus on Periprosthetic Joint Infection, and the CDC, which recommends reducing infections by maintaining normothermia. DX2, Mont Dep. at 235:4–240:6. Moreover, Dr. Mont's opinion is supported by the United States Food & Drug Administration (FDA) which recently stated, "The FDA is reminding health care providers that using thermoregulation devices during surgery, including forced air thermoregulating systems, have [sic] been

demonstrated to result in less bleeding, faster recovery times, and ***decreased risk of infection for patients***."[13] ECF No. 751-1 at 2, United States Food & Drug Administration letter "Forced Air Thermal Regulating Systems: Healthcare Provider Letter- Information About Use" (emphasis added).

III. DR. MONT'S OPINIONS ARE PROPER REBUTTAL AND WILL ASSIST THE TRIER OF FACT.

All of Dr. Mont's opinions, which critique opinions offered by Plaintiffs' experts, fit properly within his role as a rebuttal expert. *See Aviva Sports, Inc. v. Fingerhut Direct Marketing, Inc.*, 829 F. Supp. 2d 802, 835 (2011) (Ericksen, J.) (a rebuttal expert's role is "to critique plaintiffs' expert's methodologies and point out potential flaws in the plaintiff's experts' reports"). His opinions that there are sources of airflow and heat generation in operating rooms that exceed the airflow and heat from the Bair Hugger system and that the Bair Hugger system is not capable of causing PJIs directly rebut Plaintiffs' experts' opinions that heated air from the Bair Hugger system causes convection currents and disrupts operating room airflow. In addition, although Plaintiffs' experts, including their orthopaedic surgeon Dr. Michael Stonnington, conclude that heat from the Bair Hugger system disrupts operating room airflow, they fail to sufficiently address the relevant scientific literature relating to sources of airflow and heat generation in the operating room. *See, e.g.*, ECF No. 751-1 at 278–82, Stonnington Rpt. at 3–7. Thus, Dr. Mont's testimony and opinions regarding his experience and the scientific literature on airflow disruption and

[13] Dr. Mont cites the August 30, 2017 FDA letter as further support of his conclusions. DX1, Mont Rpt. at 158.

heat generation in the operating room provide missing information that will assist the trier of fact in resolving facts at issue in the litigation. *See Daubert*, 509 U.S. at 591–93.

IV. DR. MONT'S OPINIONS AND TESTIMONY MEET THE REQUIREMENTS OF *FRYE-MACK*.

In addition to meeting the Federal Rules' threshold for admissibility, Dr. Mont's opinions and testimony are admissible under Minnesota Rule 702 and the *Frye-Mack* standard as expressed in *Goeb v. Tharaldson*, 615 N.W.2d 800, 814 (Minn. 2000). As discussed above, Dr. Mont properly relies upon his experience, as well as his review and analysis of scientific literature. Moreover, his opinions are consistent with independent reviewers such as the United States FDA, the Association of periOperative Nurses (AORN), the 2013 Proceedings of the International Consensus Meeting on Periprosthetic Joint Infection. *See*, ECF No. 762 at 20–24. Dr. Mont's opinions and testimony are therefore both "foundationally reliable" and "generally accepted" in the CFD and airflow visualization community. *See Goeb*, 615 N.W.2d at 814. Further, Minnesota law is consistent with federal law in holding that "[t]he function of rebuttal testimony is to explain, repel, counteract or disprove evidence of the adverse party." *Signature Flight Support Corp. v. Cty. of Ramsey*, No. 62-CV-14-3089, 2017 WL 1377751, *1 (Minn. Tax Apr. 7, 2017) (quoting *Aviva Sports, Inc.*, 829 F. Supp. 2d at 834)); *accord Whitney v. Buttrick*, 376 N.W.2d 274, 278 (Minn. App. 1985) (granting new trial based on district court's improper exclusion of rebuttal expert testimony). Thus, it is entirely appropriate for Dr. Mont to critique Plaintiffs' experts' opinions, and he should be permitted to do so at trial in Ramsey County as well as in the federal MDL.

CONCLUSION

Dr. Mont offers opinions concerning the Bair Hugger system and the operating room environment based on his having performed over 10,000 surgeries, his professional leadership activities, and his extensive research and writing on infection reduction. He reasonably relies upon the combination of his experience and his analysis of scientific literature related to the Bair Hugger system, infection reduction and operating room best practices to form his opinions. Dr. Mont's expert testimony and opinions are grounded in reliable methodology and are therefore admissible under Fed. R. Evid. 702 and *Daubert*, as well as Minnesota law. Accordingly, Plaintiffs' motion should be denied.

Dated: October 3, 2017

Respectfully submitted,

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